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EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,494	CHAUDHURI ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-34 is/are rejected.

7)☒ Claim(s) 35 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/17/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges receipt of application 10/616494 on 07/10/2003. Claims 1-35 are pending and are accordingly presented for examination on the merits.

Applicant is advised to make the following corrections.

In the Abstract, the period after the word "Emblicanin A" should be removed.

In claim 1, the period after the word "Emblicanin A" in step (a) should be removed.

In claim 35, the period after the word "obtained" in step (1) should be removed and replaced with a semi-colon. Also in claim 35, percentages should be specified (e.g., % by weight).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "UV" in claim 7 is used by the claim to mean "wavelengths from

410 nm to 650 nm", while the accepted meaning is "wavelengths from 190 nm to 400 nm" with respect to measuring the UV spectrum with a standard UV spectrophotometer. The term is indefinite because the specification does not clearly redefine the term.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 9, 11, 14, 16, 17, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ghosal U.S. Patent No. 6,124,268.

Claim 1 is drawn to a anhydrous composition comprising (a) an antioxidant comprising over 40% by weight of hydrolysable tannins comprising Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin, (b) a substantially anhydrous or non-aqueous liquid vehicle functioning to disperse the antioxidant.

Ghosal discloses an antioxidant composition derived from the fruit of the *Emblica officinalis* plant (Column 2, lines 20-32). In one disclosure, a liposomic gel formulation comprised of 0.5% CAPROS-lecithin (1:1) complex prepared by mixing 1mM CAPROS with a lecithin in peroxide free ether or toluene (Column 4, lines 52-54 and column 5 lines, 58-67). The composition of CAPROS is: Emblicanin-A and Emblicanin-B (35-55%); Punigluconin (4-15%); Pedunculagin (10-20%); Rutin (5-15%); and gallo-ellagitannoids (10-30%) (Column 2, lines 37-44) and is the only antioxidant disclosed for this formulation thus comprising over 40% by weight of antioxidants in the composition. Lecithin sequesters the antioxidant and is dispersed in a volatile, substantially anhydrous organic solvent (peroxide free ether or toluene) thus meeting the limitations

of claim 1. Lecithin is an organic ester thus meeting the limitation of instant claim 8 and it acts to form a structural liposome further meeting the limitation of instant claim 11.

Instant claim 14 is drawn to an anhydrous composition according to instant claim 1, further comprising a gelling agent. Instant claim 16 recites an anhydrous composition according to instant claim 11, further comprising a gelling agent. Instant claim 15 is directed to an anhydrous composition of instant claim 16, wherein said gelling agent comprises at least one member selected from the group consisting of silicone elastomers, gelled natural and mineral oil systems, and gelled mineral oil and polymer systems. Instant claims 18, 23 and 24 are drawn to an anhydrous composition of instant claims 1, 16 and 17, respectively, further comprising at least one sunscreen.

Ghosal discloses a composition comprised of propylene glycol isoceteth-3 acetate (glycols are a structural agent defined by applicant on pages 5 and 6 of the instant specification); octyl methoxycinnamate (a known sunscreen agent); benzophenone-3; homomenthyl salicylate; steareth-2; acrylates/C10-30 alkyl acrylate crosspolymer; synthetic wax (waxes can be used as a structural agent as defined by applicant on page 7 of the instant specification); dimethicone (a silicone elastomer that can be used as a gelling agent as defined by applicant on page 8 of the instant specification); and CAPROS (Column 8, lines 46-65; Example 11 Phase A-1). The mixture of these components meets the limitations of instant claims 1, 8, 9, 11, 14, 16, 17, 23, and 24.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghosal U.S. Patent No. 6,362,167 and Vatter et al. U.S. Patent No. 6,475,500.

Ghosal discloses an extract blend that comprises by weight 35-55% of Emblicanin-A and Emblicanin B; about 4-15% of Punigluconin; and about 10-30% of Pedunculagin; about 0-15% of Rutin and about 10-30% of tannoids of gallic/ellagic acid (Column 8, lines 12-20). The Examiner considers 0.001 to 0.01% Rutin within the range 0 to 15% Rutin specified by Ghosal.

Ghosal does not expressly teach a composition comprising the antioxidant extract blend and a substantially anhydrous or non-aqueous liquid vehicle further comprising a sunscreening agent or bismuth oxychloride.

The features recited in applicant's claim 3 are noted. The difference between claim 3 and Ghosal is that Ghosal does not expressly disclose 20-35 wt% Emblicanin A and 10-20 wt% Emblicanin B. Ghosal discloses a combined amont of 35-55 wt% of the two ingredients, wich is sufficient to encompass the combined amounts of said ingredients in applicant's claim 3. Additionally, at for example, 40 wt% total of the two ingredients, as disclosed and suggested by Ghosal, equal amounts of the two

ingredients would be 20 wt% each. Hence, given the variability of extract content, which would be expected by the ordinary skilled artisan in this field, the percentages of Emblicanin A and B as set forth in claim 3 would have been fairly suggested from Ghosal's teachings.

The maximum absorbance feature recited in applicant's claim 7 is noted. Nowhere else in applicant's disclosure is this feature explained any further. However, applicant does state that "present invention is applicable to all types of extracts of Phyllanthus emblica" (specification page 1, lines 14-15). Applicant also states that the cited reference by Ghosal does in fact disclose extracts of Phyllanthus emblica (specification page 1, lines 11-14). Therefore, given that Ghosal's extract contains the same exact antioxidants as required by applicant's claim 1, the analytical characteristics set forth in applicant's claim 7 (dependent on claim 1) are presumed to be characteristics that must necessarily be present in Ghosal's extract and its antioxidants, particularly in view of applicant's statement that Ghosal's extract is suitable and further in view of absence of any other evidence regarding the maximum absorbance disclosure. The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

Vatter et al. disclose an anhydrous cosmetic composition that improves skin color, texture and feel which is prepared by mixing: DC9040 cross linked elastomer gel (a dimethicone gelling agent); cyclomethicone (a silicone oil); silica, titanium dioxide (a sunscreen agent), iron oxide (Ronasphere LDP); isoeicosane (permethyl 102A); alkyl methicone (DC AMS C30 wax) (a structural agent); iron oxides-silicone coated; and titanium dioxide-silicone coated (Column 30, lines 47-64 and Column 32, lines 5-6). Vatter et al. disclose that bismuth oxychloride is a suitable agent to add to the composition (Column 13, lines 9-10). Vatter et al. disclose that polyethylene glycol is a suitable humectant to add to the composition (Column 11, lines 60-61).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to produce an anhydrous composition comprised of the antioxidant composition of Ghosal, derived from the fruit of the *Emblica officinalis* plant containing 0-15% Rutin and the anhydrous skin lotion of Vatter et al. to produce the instant invention. One having ordinary skill in the art would have been motivated to do this because Vatter et al. suggest that antioxidants can be incorporated into the compositions of their disclosure (Column 23, lines 55-67).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Claim Rejections - 35 USC § 103

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,649,150 in view of Vatter et al. U.S. Patent No. 6,475,500.

U.S. Patent No. 6,649,150 (hereafter referred to as the 150' patent) discloses a powder composition consisting essentially of by weight: 20-35% Emblicanin A, 10-20% Emblicanin B, 15-30% Pedunculagin and 3-12% Punigluconin 0.001 to 0.01% by weight of Rutin, less than about 1% flavonoids, said weight percentages having an average deviation of not more than 10% (Claim 1; column 13, lines 37-42) and characterized by an optical density of 0.8 at wavelength 410 nm, 0.1 at wavelength 470 nm, 0.08 at wavelength 530 nm, 0.09 at wavelength 590 nm and 0.02 at wavelength 650 nm (Claims 11-15; column 14, lines 4-20). The 150' patent further discloses a formulation according to claim 1 and a cosmetically or pharmaceutically acceptable carrier (Claims 5 and 17, column 13, lines 48-50 and column 14, lines 23-25). The powder of the composition consists of essentially over 40% by weight of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and less than about 1% by weight of flavonoids (Claim 18; column 14, lines 26-29) and the powder according to claim 18 can consist essentially of by weight 50-80% of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and less than about 0.06% by weight of flavonoids (Claim 19; column 14, lines 30-33). In addition, the formulation can further comprise a photoprotective agent (sunscreen) (Claim 8; column 13, lines 57-59).

The 150' patent does not expressly disclose an anhydrous composition comprising an antioxidant comprising over 40% by weight of hydrolysable tannins comprising Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and a substantially anhydrous or non-aqueous liquid vehicle functioning to disperse the antioxidant or expressly disclose the addition of bismuth oxychloride.

Vatter et al. is relied upon as described above.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made modify the antioxidant composition of the 150' patent by mixing it in a non-aqueous substantially anhydrous liquid vehicle taught by Vatter et al. to produce the instantly claimed invention. One of ordinary skill in the art would have been motivated to do so because the 150' patent suggests that the composition can be formulated with a cosmetically or pharmaceutically acceptable carrier (Claim 5). One of ordinary skill in the art would have found the disclosure of Vatter et al. and produced the instant invention.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Double Patenting

Claims 1-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 11-15 and 17-19 of U.S. Patent No. 6,649,150 in view of Vatter et al. U.S. Patent No. 6,475,500.

The 150' patent discloses a powder composition consisting essentially of by weight: 20-35% Emblicanin A, 10-20% Emblicanin B, 15-30% Pedunculagin and 3-12% Punigluconin 0.001 to 0.01% by weight of Rutin, less than about 1% flavonoids, said weight percentages having an average deviation of not more than 10% (Claim 1) and characterized by an optical density of 0.8 at wavelength 410 nm, 0.1 at wavelength 470 nm, 0.08 at wavelength 530 nm, 0.09 at wavelength 590 nm and 0.02 at wavelength 650 nm (Claims 11-15). The 150' patent further discloses a formulation according to claim 1 and a cosmetically or pharmaceutically acceptable carrier (Claims 5 and 17). The powder of the composition consists of essentially over 40% by weight of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and less than about 1% by weight of flavonoids (Claim 18) and the powder according to claim 18 can consist essentially of by weight 50-80% of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and less than about 0.06% by weight of flavonoids (Claim 19). In addition, the formulation can further comprise a photoprotective agent (sunscreen) (Claim 8).

The 150' patent does not expressly disclose an anhydrous composition comprising an antioxidant comprising over 40% by weight of hydrolysable tannins

comprising Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and a substantially anhydrous or non-aqueous liquid vehicle functioning to disperse the antioxidant or expressly disclose the addition of bismuth oxychloride.

Vatter et al. is relied upon as described above.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made modify the antioxidant composition of the 150' patent by mixing it in a non-aqueous substantially anhydrous liquid vehicle taught by Vatter et al. to produce the instantly claimed invention. One of ordinary skill in the art would have been motivated to do so because the 150' patent suggests that the composition can be formulated with a cosmetically or pharmaceutically acceptable carrier (Claim 5). One of ordinary skill in the art would have found the disclosure of Vatter et al. and produced the instant invention.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Allowable Subject Matter

Claim 35 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1-34 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EVA

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